PATENT APPLICATION
Attorney Docket No. AP-1
[1064 001 301 0202]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE
BOARD OF PATENT APPEALS AND INTERFERENCES

Inventor:	**Arthur Papier et al.**	Conf. No.:	**4087**
Application No.:	**09/919,275**	Group Art Unit:	**3621**
Filed:	**July 31, 2001**	Examiner:	**Kambiz Abdi**

Title: **SYSTEM AND METHOD TO AID DIAGNOSES USING CROSS-REFERENCED KNOWLEDGE AND IMAGE DATABASES**

Mail Stop: **Appeal Brief – Patents**
Honorable Commissioner for Patents
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Sir:

<u>REPLY BRIEF FOR APPELLANT S</u>

This Reply Brief is being submitted on behalf of Appellants, Arthur Papier and Nancy Weyl, in response to the Examiner's Answer dated September 6, 2006, and in conjunction with the previously-submitted amendment correcting the Appealed Claims Appendix (submitted October 20, 2006), both in connection with the above-identified, pending application and appeal.

In the event that any additional fees are required as a result of this submission, the Office is hereby authorized to charge such fees to the USPTO Deposit Account for Basch & Nickerson LLP, Deposit Account 50-2737.

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I. STATUS OF CLAIMS:

Claims 1 - 24 and 28 remain rejected in the application. Claims 25 – 27 and 29 - 30 have been withdrawn from consideration pursuant to a restriction set forth in the Office Action of October 14, 2004. The rejections of claims 1 - 24 and 28 are appealed herein.

II.   GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL:

Claims 1 - 15, 19, 22 - 24 and 28 stand rejected under 35 USC §103(a) as being unpatentable over US 5,437,278 to Wilk (Wilk) in view of US 4,945,476 to Bodick et al. (Bodick).

Claims 16 - 18 and 20 - 21 stand rejected under 35 USC §103(a) as being unpatentable over Wilk in view of Bodick and further in view of US Application 2003/0036683A1 to Kehr et al. (Kehr); *and further in view of either US Provisional Application 60/200853 to Kehr et al. (Kehr Prov. A) or US Provisional Application 60/214688 to Kehr et al. (Kehr Prov. B) as implied by the Examiner's Answer.*

III.   ARGUMENTS:

Appellants wish to note that the Examiner's Answer mailed Sept. 6, 2006, while appearing to respond to Appellants' Brief on Appeal, is largely a verbatim copy of the rejections and conclusions set forth in the Final Office Action in this matter. As a result the Examiner's Answer is urged to be, to a large extent, unresponsive to the arguments set forth by Appellants in the Appeal Brief. Appellants have, however, taken this opportunity to briefly address the failures of the rejections, as well as to address the <u>new ground of rejection that appears to have been introduced in the Examiner's Answer</u>, albeit not specifically identified as such by the Examiner.

Introduction

Appellants respectfully direct the Board's attention to the Summary of Claimed subject Matter as set forth in the Appeal Brief. Moreover, Appellants continue to urge, as more specifically set forth below, that the references relied upon for the rejections do not address the invention as a whole, the need for a system to handle the uncertainty and ambiguity of medical diagnosis, or the manner in which Appellants have uniquely addressed such a need. As set forth in the application, the claimed invention facilitates real-time decisions (Specification, p. 3, lines 13-14). Conversely, the references fail to provide for or arrange images relating to a plurality of different diagnoses or to reorganize the images into a compact information space. The ability to visually scan, compare and traverse the visual complexity in relation to many possible diagnoses is simply not believed to be possible and, thus, cannot support the rejections for reasons as will now be further described.

Questions Presented

Several questions remain in this appeal:

First, whether claims 1 - 15, 19, 22 - 24 and 28 were properly rejected under 35 USC §103(a) as being unpatentable over Wilk in view of Bodick, including

> (a) whether the rejection under 35 USC §103(a) improperly combines two patents that teach away from one another,

(b) whether the rejection under 35 USC §103(a) applies an improper standard in reaching the conclusion of obviousness, and

(c) whether the rejection under 35 USC §103(a) , even if the combination is determined proper, omits elements recited in the rejected claims; and

Second, whether claims 16 - 18 and 20 - 21 were properly rejected under 35 USC §103(a) as being unpatentable over Wilk in view of Bodick and further in view of Kehr, including not only the questions posed above, but also

(a) whether the rejection improperly relies upon a "reference" (Kehr) not made of record and available only after Appellants' priority date , and

(b) whether the Examiner's setting forth, for the first time in the Examiner's Answer, a reliance on teachings of *Kehr Prov. A (60/200853)* & *Kehr Prov. B (60/214688)* documents in support of the prior rejection and Official Notice (i) constitutes a new grounds for rejection, and (ii) whether such a rejection is incomplete for failing to make of record and provide copies of the non-published documents reviewed by the Examiner in supporting the rejection.

Rejection Under 35 U.S.C. §103

Appellants continue to submit that the claimed invention is unique and has extensive application and utility. Under section 35 U. S. C. §103, the Patent and Trademark Office must make out a case of *prima facie* obviousness. In *Panduit Corp. v. Dennison Mfg. Co., 1 USPQ2d 1593 (Fed. Cir. 1987)*, the court stated that "[w]ith the involved facts determined, the decision maker confronts a ghost, i.e. "a person having ordinary skill in the art", not unlike the "reasonable man" and other ghosts in the law. To reach a proper conclusion under section 103, the decision maker must step backward in time and into the shoes worn by that "person" when the invention was unknown and just before it was made. In light of *all* the evidence, the decision maker must then determine whether the patent challenger has convincingly established, 35 U.S.C. 282, that the claimed invention as a whole would have been obvious at that time to that person. 35 U.S.C. §103. The answer to that question partakes more of the nature of law than of fact, for it is an ultimate conclusion based on a foundation formed of all the probative facts. If itself a fact, it would be part of its own foundation. . . . .a prior patent must be considered in its entirety, i.e., as a *whole,* including portions that would lead away from the invention in suit." The mere fact that

references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills, 16 USPQ2d 1430 (Fed. Cir. 1990; emphasis added)).* See also *In re Gordon, 221 USPQ 1125, (Fed. Cir. 1984); Jones v. Hardy, 220 USPQ 1021, (Fed. Cir. 1984).*

Finally, the Examiner may not use the Appellants' disclosure as a recipe for selecting portions of the "prior art" to construct Appellants' claimed invention. A piecemeal reconstruction of the prior art patents in light of Appellants' disclosure is not a basis for a holding of obviousness, *In re Kamm et al., 172 USPQ 298 (CCPA, 1972).* Moreover, this teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Appellants' disclosure. *In re Vaeck, 20 USPQ2d 1438 (Fed. Cir. 1991).*

Were claims 1 - 15, 19, 22 - 24 and 28 properly rejected under 35 USC §103(a) over Wilk in view of Bodick, (1st Question)

The disclosures of Wilk and Bodick are both directed to automated medical diagnosis. Appellants respectfully contend that the inherent ambiguity of medical diagnosis requires, not automated diagnosis, but a knowledge presentation facilitating rapid comparison and perception by the user - an essential distinction set forth in the rejected claims of the present application. The ability of the human eye to make visual comparisons between thousands of possibilities is impossible, yet when choices are constrained to a few, recognition is near instantaneous. The purposeful design of the claimed system and method set forth in the claims of the instant application combines medically relevant knowledge to filter or "presort" the search results to a manageable number of diagnostic possibilities. This combination of a medical knowledge base interwoven with visual representations of possible diagnoses, which provide the ability for a system user to visually match what the user sees displayed relative to the patient, is not believed to be described in Wilk, Bodick or any of the references made of record. Appellants further note that the display of a plurality of images (e.g., claim 1), for example in the claimed diagnostic stack (e.g., claim 6), constitute patentably distinguishable aspects of Appellants' invention. While there may be decision support systems used in human medicine, none support presentation of visual knowledge using a plurality of diagnoses and images, moreover none allow for the display of visual complexity, reorganized to the user search as recited in the limitations of the current claims.

With respect to the first question, Appellants submit that several sub-questions must be considered in order to determine whether claims 1 - 15, 19, 22 - 24 and 28 were properly rejected.

(a) Improper combination of patents that teach away from one another

Appellants respectfully submit that the rejection under 35 USC §103(a) must fail because Wilk and Bodick are not properly combined to establish *prima facie* obviousness. More specifically, the two patents teach away from one another and fail to support the combination/modification urged as the basis for the rejection. In response to Appellants arguments set forth in the Brief, the Examiner's Answer repeats (essentially in verbatim) the Examiner's response in the Final Office Action of May 2005 (p. 3, item 2). Notably that prior response did not address Appellants' argument relative to the improper combination of Wilk and Bodick, particularly in view of Wilk teaching away from Bodick.

Wilk is clearly directed to a medical diagnostic system described as having a device 20 for monitoring and measuring a biological or physiological parameter, transmitting the parameters to a computer 24, and ultimately communicating a medical diagnosis as determined by the computer. As set forth at col. 3, lines 58 – 63, "[b]ecause diagnoses are made by computer in accordance with the present invention, it is frequently unnecessary to have a doctor present during data taking (symptom recording and measurement) and communication of the diagnosis to the patient." (emphasis added).

Bodick, directed to the creation and editing of a knowledge base for use as an aid to the cognitive process of diagnosis, discloses the creation of a knowledge base containing both pictorial images and textual information therein (col. 2, lines 39-40), along with a system to use such information in a medical diagnosis. Appellants continue to urge that when taken in context, Wilk does not suggest the use or display of an image as described by Bodick (at best the cited language indicates a reduction in the time for examination, not necessarily diagnosis) – one of ordinary skill in the art would not be so motivated as the "Computer 24 is operated … to derive a diagnosis..." (Wilk; col. 4, lines 65-69). It also remains unclear what would have motivated one skilled in the art to modify Wilk's automated medical diagnostic system to make it "unautomated" and used for searching of case data as required by Bodick. No motivation is found in Bodick to suggest making Wilk's automated diagnostic

system a manual system. Rather, Appellants respectfully urge that it the claims of the instant application that have been used as the "recipe" from which elements of the cited patents have been selected. (*see In re Kamm et al., In re Gordon, Jones v. Hardy, and In re Vaeck as referenced above*). Accordingly, Appellants continue to urge that the proposed modification of Wilk in view of Bodick is improper in view of the teaching away by Wilk, and independent claims 1, 3, 5 and 28 are respectfully urged to be in condition for allowance.

(b) Improper standard used in reaching the conclusion of obviousness

Appellants previously challenged the Examiner's basis for the proposed combination/modification of WIlk in view of Bodick, and in response the Examiner's Answer indicates that Wilk is interpreted as disclosing an aid to diagnosis. As noted above, and previously (e.g., Response After Final), this is a mischaracterization of the teachings of Wilk as a whole, which is identified as being directed to a "medical diagnostic system" (e.g., col. 4, line 29) "...to derive a diagnosis..." (col. 4, line 69), where the relationship to a physician is stated as "eventually sees a physician for confirming the diagnosis" (col. 3, lines 64-65) - not as an aid.

As the basis for the combination or modification of Wilk in view of Bodick, the Examiner states in the rejection, after having set forth where aspects of the claimed invention are alleged to be taught by Bodick, that"

> "Thus, it would have been obvious to one of ordinary skill in the art at the time of appellant's [sic] invention to modify the system of Wilk and incorporate the ability to identify a subset of possible diagnoses based upon a sample of characteristics and further to display the images or other data related to the subset as taught by Bodick et al. Bodick et al provides motivation by indicating that these features would benefit doctors or physicians by assisting them in searching information that would help them in diagnosing a medical condition (Col. 1, lines 10-16; Col. 2, lines 1-6)."
> *Examiner's Answer (p. 3 bottom – p. 4 top)*

The diagnostic system disclosed by Wilk is not designed to assist a user in identifying a diagnosis, and disregards the need to tolerate ambiguity and complexity of medical diagnoses. Appellants respectfully stress this distinction and further note that the patient–physician interaction requires timely decisions facilitated by the claimed

invention where, for example, user-entered characteristics are employed to identify a subset of diagnoses, which are then used to automatically reorganize an information space of an image database for presentation to the user, and the presentation is accomplished through the concurrent presentation of a plurality of images for user review.

Appellants continue to question how one of skill in the art (which may or may not be a "medical professional" as apparently urged by the Examiner at p. 10 (line 8) of the Examiner's Answer) would be motivated to modify Wilk to add identification of a subset of diagnoses or to display images relating to the subset, when Wilk clearly taught the communication of "a diagnosis" to the patient (e.g., col. 3, line 62) and the communication of the diagnosis via output device (Printer 30; Fig 1) in a step 40 (see e.g., col. 5, lines1-3). What motivation would there be to display Bodick's images to a patient that has been diagnosed by the Wilk system, particularly when Wilk indicates that the computer conducts an image comparison (col. 2, lines 46-56)?

As noted above, Wilk's automated diagnostic system teaches away from an aid in a visual diagnostic process as recited by the rejected claims. If that were not the case, why would Wilk indicate that the diagnosis is made by the computer? In the Final Office Action, and again in the Examiner's Answer, the Examiner urges that WIlk's suggestion that the diagnosis may be confirmed "[supports] the idea that the invention may be used as an aid rather than a final diagnosis." (Ex. Answer; p. 10, line 12). Appellants question whose "idea" is being supported – Wilk's, Bodick's, or perhaps more likely, Appellants' idea as set forth in the application and rejected claims? Appellants further urge that Wilk's use of the term "confirm" clearly establishes that a diagnosis was made, and the indication that it is "confirmed" by a physician further supports the intent of Wilk to provide an automated medical diagnostic system and teaches away from a subset including a plurality of diagnoses. In light of Appellants' prior arguments, as well as those present herein, it is apparent that <u>the motivation relied upon for the proposed modification of Wilk is found in the instant application, not in any teaching or suggestion that would have been known to one skilled in the art without the benefit of Appellants' application</u>. Accordingly, Appellants respectfully maintain that the rejection applies an improper standard in the conclusion that it was obvious to combine or modify the Wilk and Bodick patents. For this reason, independent claims 1, 3, 5 and 28 are respectfully urged to be non-obvious and in condition for allowance.

(c) Omission, in the rejection, of elements recited in the rejected claims

While Wilk does disclose the storage of images, it does not disclose the storage of images in an image database, nor the cross-referencing of the image database with a knowledgebase for purposes of assisting in the diagnostic process as recited in the rejected independent claims (e.g., claims 1, 3, 5 and 28). Appellants' review of Wilk did not identify reference to a database, let alone separate image and knowledge databases. Rather, what was found was reference to bulk storage and memory (e.g., 28 in Fig. 1), which clearly do not teach the separately recited image database and knowledge database found in the rejected claims.

The Examiner further urges, at page 10 of the Examiner's Answer, in the second paragraph of Section (10), Response to Argument, that Wilk's teaching of image comparison "clearly suggests that the computer processing or knowledgebase is separate from the stored images as one skill [sic] in the art would understand the system." Appellants respectfully contend that the Examiner has improperly characterized the teachings of Wilk and that no support has been set forth to establish that one of skill in the art would have identified a knowledge database in Wilk, let alone a knowledge database separate from the image database. There simply is no teaching or suggestion in Wilk of the recited limitation of an image database and a knowledge database, where the knowledge database is cross-referenced to the image database (e.g., claim 1), nor has the Examiner demonstrated how or why one of skill in the art would have arrived at the understanding that has been alleged in support of the rejection. Thus, *prima facie* obviousness cannot be established based upon Wilk's alleged teachings.

As previously conceded by the Examiner, Wilk fails to disclose identifying a subset of diagnoses and using the subset of diagnoses to reorganize an information space of the image database for concurrent presentation of a plurality of images for user review via the user-Interface as set forth in the appealed claims.

To make up for the acknowledged gap in Wilk's teachings, the rejection relies upon Bodick and urges that Bodick teaches the limitations of the independent claims not taught by Wilk. Bodick discloses the creation of a knowledgebase containing both pictorial images and textual information therein (col. 2, lines 39-40). The system is further described as being dynamic; to permit the addition of newly discovered characteristics observed in patients and deletion of characteristics having little

diagnostic importance. As Bodick points out, the disclosed knowledge base is distinct from a classic database (col. 3, lines 12-16).

Although Bodick does describe alternative methods of accessing the knowledge base (by cases having specific features or by cases in which a particular disease was diagnosed; col. 5, lines 42-48), Appellants respectfully submit that such a teaching does not give rise to the recited limitations of "automatically identify[ing], from a plurality of possible diagnoses, a subset including a plurality of diagnoses that are consistent with the characteristics." It is further urged by Appellants that Bodick and Wilk both presuppose that there is always a diagnostic answer, when in fact there is often no definitive answer in human medicine.

Accordingly, particularly with regard to the claimed limitation of "automatically reorganizing an information space of said image database for concurrent presentation of a plurality of images for user review," Appellants respectfully submit that no such teaching is found in Bodick, and that Bodick, in fact, teaches away from such a limitation. For example, at col. 2, lines 59-61, where a comparison is described between "one patient or sample" and a "previous patient or sample" there is nothing to suggest that more than a single representation is displayed at one time – resulting in a user having to remember a prior image(s). Similarly, col. 6, lines 19-22 of Bodick clearly indicate that information from a single record is displayed – not the concurrent presentation of a plurality of images for user review, reflecting a subset of diagnoses, as recited in the rejected claims (e.g., claim 1).

Even considering, *in arguendo*, a combination of Wilk in view of Bodick, at most the combination teaches the use of a common collection of data or knowledge for an automated medical diagnostic system. The modifications "suggested" by Bodick (with arguments to the contrary presented previously) would, at most, result in a system where the data of the Wilk system may be searched and text and/or an image from a case displayed to a user of the system as suggested by Bodick. Such a combination or modification does not, however, teach the automated identification of a subset having a plurality of diagnoses, in response to characteristics, let alone using the subset of diagnoses, automatically reorganizing an information space of the image database for concurrent presentation of a plurality of images for user review. To assure proper consideration of these limitations, Appellants direct the Board's attention to pages 25 – 28 of the Specification, and to the following representations of

Figures 12 and 14. The figures illustrate the response of the claimed system to additional characteristics (findings) to depict the reordering of the information space as illustrated by the change in images/ordering in response to the addition of the "obesity" characteristic in window 292.
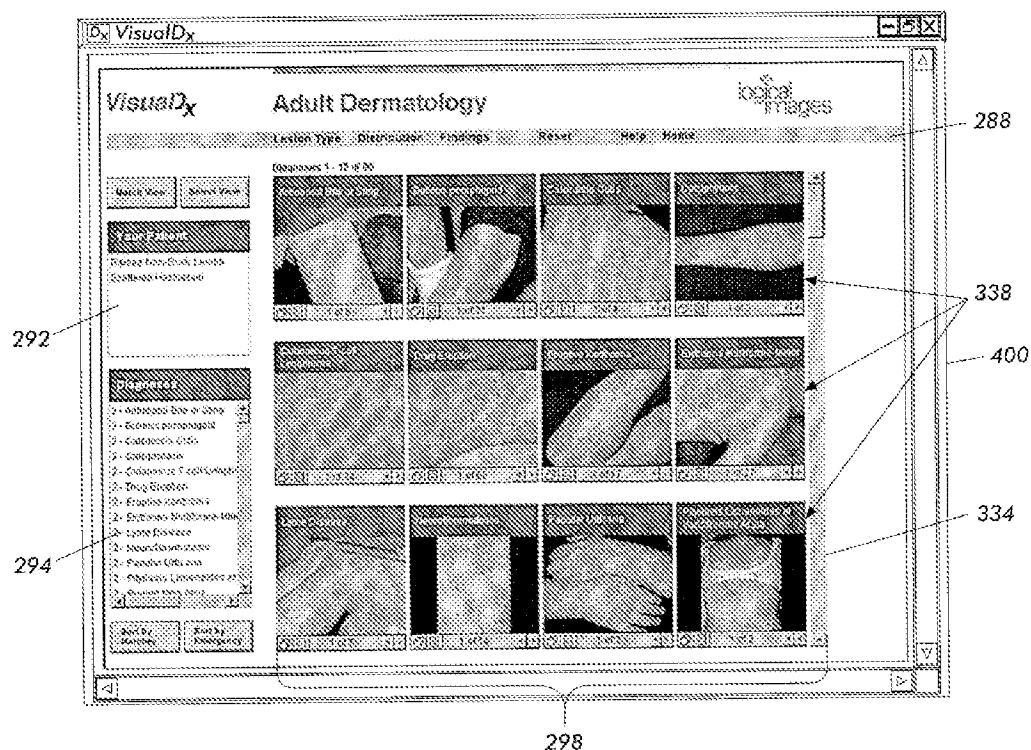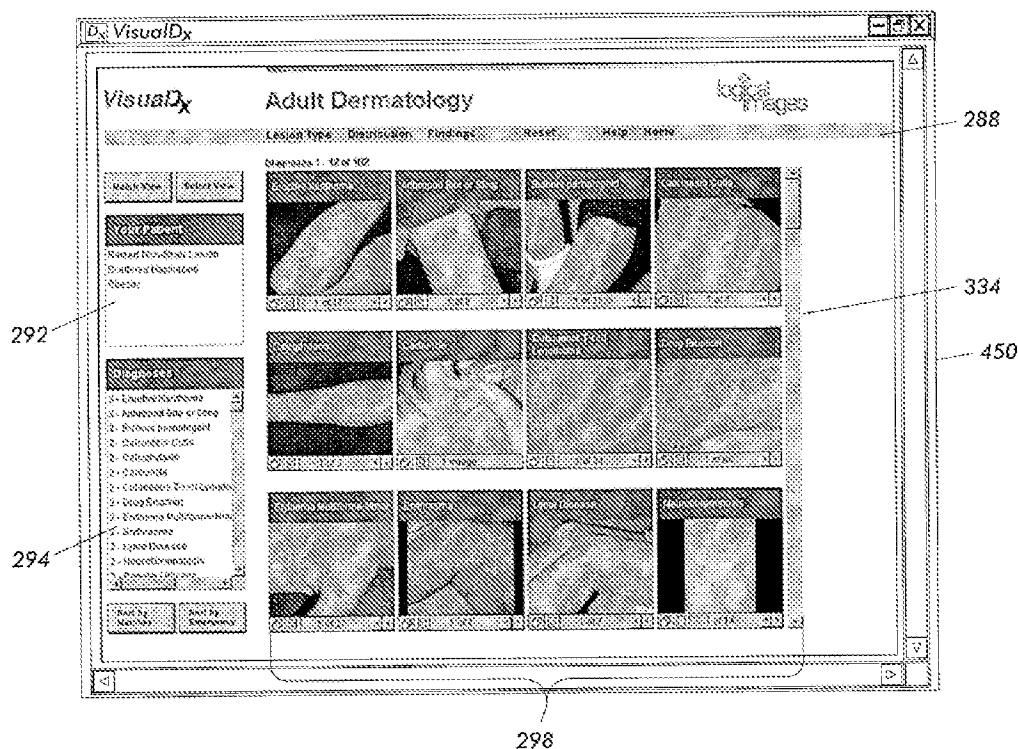

FIG. 12

FIG. 14

Clearly, neither Wilk nor Bodick teaches the automatic reordering of an information space and concurrent presentation of a plurality of images for user review, as recited in independent claims 1, 3, 5 and 28. The claims are, therefore, patentably distinguishable over the arguable combination.

The Examiner's Answer, like the Final Office Action urges, that Bodick's teaching of side-by-side presentation of image and text information "seems to suggest that a concurrent display of a plurality of images." (Examiner's Answer p. 11, lines 9-10) Appellants respectfully maintain that "seems to suggest" is not the proper standard for an obviousness rejection, and that for this reason the rejection should be overturned.

Moreover, it does not appear, from the numerous display examples shown in Bodick, that there is a display depicting a plurality of images. Moreover, Bodick teaches, relative to Figs. 13A, 14 and 14A, "[t]he flow chart of FIG. 14A, which is reached from the flow chart of FIG. 13A, depicts how this viewing of an image is carried out, and FIG. 14 illustrates a display screen of what is viewed by the expert." (col. 23, lines 65-68; emphasis added). Thus, in spite of the Examiner's urging to the contrary, Bodick

teaches a single image display and fails to teach or suggest the concurrent presentation of a plurality of images associated with a subset of diagnoses for user review as recited in the rejected claims. In view of the above-noted arguments in traversal of the rejection, Appellants' respectfully request that the Board overturn the rejection of claims 1, 3, 5 and 28 and indicate their allowance.

With regard to dependent claims 2 and 4, it is notable that the Examiner's Answer does not appear to address Appellants' remarks as previously set forth in the Appeal Brief. Appellants continue to urge that the Examiner has mischaracterized the search capability of Bodick. Claims 2 and 4 recite automatically reorganizing the information space in response to a user's modification of a descriptive characteristic. The recited feature is depicted, for example, in Figures 7 and 8 and described at page 24 of the as-filed application, and as also described above in Figures 12 and 14 – where a user's selection or entry of a descriptive characteristic results in the reorganization of the information space and alteration of the images displayed. No such teaching has been identified or illustrated in Bodick.

Independently considering the rejection of claims 6 – 11, the Examiner acknowledges that Wilk fails to teach an image stack, yet maintains that Bodick discloses a diagnostic image stack, as recited in the rejected claims, by disclosure of a diagnostic tree in Figure 26. Figure 26 of Bodick is excerpted below for convenience, as is the description of the figure from column 21 (lines 17-49).

FIG.26
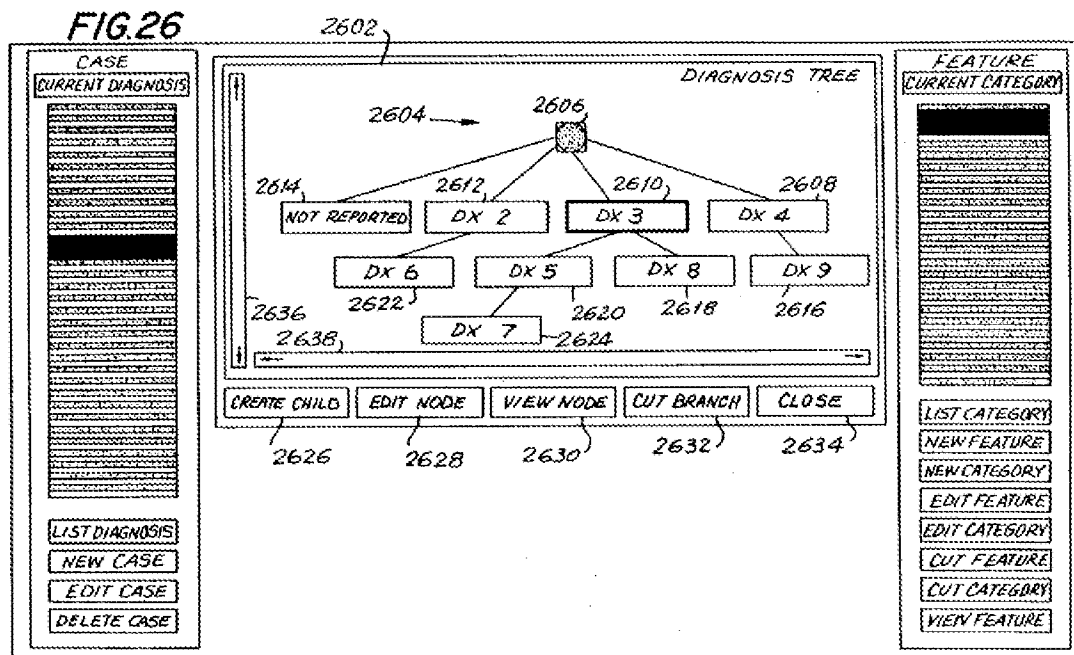
the current category from the dictionary.

Home screen 200 is provided with a diagnosis button 244, the actuation of which causes monitor 106 to display a so-called diagnosis tree. This tree is created by 20 the expert and is used to verify the accuracy by which diagnoses are made on the basis of observed features and diagnoses which are precedent. An example of an existing diagnosis tree in illustrated in FIG. 26, and FIGS. 27-29 illustrate the manner in which the diagno- 25 sis tree may be expanded or edited. Since each case record includes a diagnosis, the diagnosis tree is a valuable tool in recognizing how one diagnosis leads to another.

A brief and simple example of the utility of this digno- 30 sis tree is as follows: Let it be assumed that, in the population of patients in which the knowledge base is interested, all of those patients have been diagnosed as having tumors. However, the tumor may be benign or malignant. In the diagnosis tree, these two diagnoses 35 may be thought of as nodes of the tree, and both are on the same level and may be thought of as "siblings". For those patients having benign tumors, the next lower level of diagnoses is based upon the observation that such diagnoses appear only in patients who have benign 40 tumors. This next lower level of diagnoses may be thought of as "children" of the preceding upper level. Similarly, the diagnosis "malignant tumor" will have dependent therefrom one or more "children" whose diagnoses are found only in patients having malignant 45 tumors. The ability to edit the diagnosis tree permits refinements based upon experience and a greater population of cases and, of course, the expert's observations of those cases.

The flow charts of the various operations and rou- 50

For purposes of comparison, Appellants respectfully contend that the alleged teaching does not give rise to the claims' "plurality of images are presented as a diagnostic image stack" as found, for example, in claim 6. The Board is further referred to Figures 8 and 12 - 15 of the instant application, and the associated description at pages 24 – 25 of the Specification, where a description of an embodiment of the invention is found.

Appellants continue to urge that Bodick is clear as to the contents of Figure 26. At col. 9, line 22, Figure 26 is described as "a display used in selecting a diagnosis tree." Appellants remain unable to determine upon what information the Examiner asserts the presence of a "diagnostic image" let alone the recited "diagnostic image stack" as set forth in the rejected claims. Appellants respectfully maintain that the hierarchy depicted in Bodick does not teach a diagnostic image stack as the term has been employed to characterize a group of images in the context of diagnostic possibilities by the instant application.

Furthermore, and as previously noted, Bodick's hierarchical "tree" structure is an information strategy that is distinct from the functionality offered by the claimed image stack of the present application, and more particularly "wherein the index is independent of the common diagnosis" as found in claim 7. The present invention permits the user to enter multiple characteristics which then result in diagnoses displayed by a number of matches (see e.g., FIGS. 12 and 14 above). Accordingly, Appellants maintain that *prima facie* obviousness has not been established relative to claims reciting the diagnostic image stack, and particularly claims 6 – 11.

Appellants further note that the Examiner's Answer fails to specifically address Appellants' arguments set forth as to claim 8, where in spite of the noted failure to disclose the limitations of claim 8, the Examiner urges that "this would have been obvious in view of the teachings of Bodick et al in an effort to offer a plurality of images to the physician in order to determine the nature of the particular disease associated with the current patient." Notably, the rejection fails to indicate to whom this would have been obvious, and what teaching or suggestion is relied upon to support such a conclusion. Absent such a basis, Appellants respectfully maintain that *prima facie* obviousness has not been established relative to claim 8.

Considering claims 19 and 22-23, the Examiner again acknowledged that Wilk and Bodick both fail to teach the alternative applications (oral medications, autopsy, crime scene) set forth in claims 19 and 22-23. In spite of the admitted failure, the rejection is maintained as obvious "for any purpose as suggested by Bodick et al for the cognitive process of diagnosis." (Examiner's Answer p. 8, lines 6-8; p. 12, bottom) Absent a teaching or suggestion of the limitations set forth in the claims, Appellants continue to respectfully maintain that *prima facie* obviousness has not been established, and they continue to independently traverse the rejections of claims 19, 22 and 23. The board is respectfully requested to overturn the rejection as to claims 19 and 22-23, there being no basis to support the rejection..

Relative to claim 28, in setting forth the rejection, the Examiner failed to establish where each of the recited limitations is taught or suggested by the references relied upon – either alone or in combination. Thus, Appellants respectfully traverse the rejection of claim 28 and contend that *prima facie* obviousness has, once again, not been established, so that claim 28 is in condition for allowance – the Board is respectfully requested to overturn this rejection as well.

Were claims 16 - 18 and 20 - 21 properly rejected under 35 USC §103(a) over Wilk in view of Bodick and further in view of Kehr (2nd Question)

With regard to the rejection of claims 16 - 18 and 20 - 21, Appellants previously questioned the Examiner's "Official Notice" as to the use of icons as set forth in the claims. Even if the use of icons was known, their use in the manner specifically recited in the rejected claims is respectfully urged to be both unknown and non-obvious.

As set forth in the rejected claims, the uses are specifically recited as:

a "symptom represented as an icon" (claim 16),

"depicting the form of a dermatological lesion" (claim 17),

"depicting a distribution of the dermatological lesions about a patient's body" (claim 18),

"the shape of an oral medication" (claim 20), and

"a color of an oral medication" (claim 21).

Absent some teaching or suggestion of the recited limitations, Appellants maintain the Official Notice was an incomplete attempt at a hindsight reconstruction of the

recited claim elements using the claims as the "recipe," and further filling in missing elements (not merely interpretations) through the improper use of Official Notice. Appellants also requested that Examiner set forth document(s) teaching all of the recited limitations, and indicate the motivation for such a combination. Absent such teachings, *prima facie* obviousness is not established and the Board is respectfully urged to overturn the rejection.

Rejection improperly relies upon a "reference" not made of record and available after Appellants' priority date

In response to Appellants noting the failure of the rejection to set forth a disclosure of all of the recited elements so as to establish *prima facie* obviousness, the Examiner now appears to be rejecting the claims based upon a <u>new grounds for rejection relying on prior provisional applications by Kehr</u>. Appellants previously noted that no such document(s) has been properly made of record or cited in the rejection. Nonetheless, the Examiner's Answer indicates that the Examiner has reviewed such documents. See Examiner's Answer; p. 12, lines 16-20. Thus, the rejection presently relies upon a US patent publication for an application that was filed well after the earliest priority date claimed in the instant application - the Kehr publication simply cannot be available as a reference, or on non-published provisional applications that have not been made or record or provided to Appellants.

Examiner sets forth, for first time, a reliance on teachings of Kehr provisional application documents in support of the rejection

Appellants further note that this failure to establish *prima facie* obviousness was noted in responses to both the Final Office Action and the Pre-Appeal Brief Conference Request. Notably, Kehr was urged (Advisory Action p. 2) as "only to support the official notice previously presented," which suggests that it need not meet the requirements of a reference. Appellants respectfully maintain that it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art to make the proposed substitution, combination or other modification – or even whether the teaching arises to what is alleged by the Examiner. The rejection indicated that Wilk and Bodick failed to teach the use of icons in the manner claimed, but urged that the use of icons in a user-interface was well known. Appellants challenged the Examiner's use of "Official Notice" as the basis for supporting an element clearly missing from the claims, and in

reply the rejection was modified to include the Kehr publication which did not have a reference date prior to Appellants' priority date. In the Examiner's Answer it appears that the Examiner now relies upon teachings of earlier provisional applications by Kehr (US Provisional Application 60/200853 to Kehr et al. (Kehr Prov. A) or US Provisional Application 60/214688 to Kehr et al. (Kehr Prov. B)). Appellants respectfully submit that <u>the Examiner's reliance on the provisional applications by Kehr is a new grounds for rejection that Applicant has not been afforded an opportunity to respond to</u>.

Appellants respectfully contend that the Kehr provisional applications, from which the Kehr published application claims priority, have not been made of record or provided to Appellants as noted above. The rejection is, therefore, incomplete, and Appellants urge that the Examiner's reliance ("examiner has reviewed the provisional application [sic] that were relied upon for effective priority dates and content ... therefore the citation of Kehr reference as supporting document for the Official Notice is both proper for the content as well as effective priority date..." Examiner's Answer p. 12, lines 16-20) on such documents, whether as part of a rejection or to support Official Notice, is improper. Appellants demonstrated that the Kehr publication was not available as of Appellants' priority filing date, and absent a showing of additional evidence the rejection of claims 16-18 and 20-21, which clearly references the Kehr Publication (2003/0036683 A1) cannot be maintained.

Appellants further urge that even if considered, *in arguendo,* the addition of Kehr or other "Official Notice" as to the allegedly known use of icons does not give rise to the use of icons in the manner(s) specifically recited in the rejected claims. Accordingly, Appellants respectfully traverse the rejection, request that the rejection be overturned by the Board, and that claims 16-18 and 20-21 be indicated as allowable.

Conclusion

As set forth above, claims 1 - 15, 19, 22 - 24 and 28 were improperly rejected under 35 USC §103(a) as being unpatentable over Wilk in view of Bodick. In the alternative, when considered *in arguendo* the rejection under 35 USC §103(a) combining Wilk and Bodick omits elements recited in the rejected claims. Second, claims 16 - 18 and 20 - 21 were also improperly rejected under 35 USC §103(a) as being unpatentable over Wilk in view of Bodick and further in view of Kehr,

particularly when the rejection improperly relies upon a "reference" available only after Appellants' earliest claimed priority date or relies upon documents not made of record in the application. In the alternative, the arguable combination of Wilk, Bodick and Kehr (publication) fails to set forth the enumerated limitations relative to the icons.

In light of the various arguments set forth above, Appellants respectfully submit that all of the questions presented should continue to be answered in the negative, that all rejections set forth should be reversed, and that Appellants' pending claims should be indicated as allowable.

Respectfully submitted,

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